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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,345	07/30/2001	Boris P. Belotserkovskii	A-69625-1/RFT/DLR	2746

7590 02/27/2004

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EXAMINER
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LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/919,345

Applicant(s)

BELOTSEKOVSKII ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/23/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 9-35 and 42-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 36-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/1/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/2003. 6) ☐ Other:

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's response to the office action filed on October 23, 2003 has been entered. The claims pending in this application are claims 1-44 wherein claims 9-35 have been withdrawn for the examination due to previous restriction requirement and species election. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment and arguments (see page 7) filed on October 23, 2003. Since claims 9-11 (species 2) are not elected by applicant in applicant's response filed on January 13, 2003 and new added claims 42-44 are identical to claims 9-11, claims 42-44 are also considered as non-elected claims. Therefore, claims 1-8 and 36-41 will be examined.

### ***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: (1) it does not identify the citizenship of Boris Belotserkovskii, who is an inventor in this instant application; and (2) applicants change their filed No. without an initial (see page 2 of Oath/Declaration). Although applicant indicates that "[A] new declaration is being preparation and will be provided at a later date", without a new oath/declaration, this objection remains.

*Specification*

3. The disclosure is objected to because of the following informalities: there are Figures 3C-1, and 3C-2 in the drawings filed on January 8, 2002. However, the specification (see page 10) only describes Figures 3C-1. Each figure, e.g., 3C-1 or 3C-2, is considered to be a separate figure and needs to be described in the specification.

Appropriate correction is required.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8 and 36-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Dayn (US Patent No. 5,929,043, published on July 27, 1999).

Dayn teaches recombinase mediated DNA therapies.

Regarding claims 1 and 2, the specification defines “analog probe” as “nucleic acids containing modifications to the natural-occurring phosphodiester linkages or modifications to the natural occurring ribose backbone” (see page 13, last paragraph). Since Dayn teaches a pair of single stranded probes having a complementary region wherein the pair of probes is coated with a recombinase and the DNA sequences of the probes have modifications on various oxygens in the phosphate backbone or modifications on the ribose (see column 1, last paragraph and column 2), Dayn discloses a composition comprising an analog probe (ie., a probe with the modifications

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on various oxygens in the phosphate backbone or modifications on the ribose) and a first recombinase coated single stranded nucleic acid probe as recited in claim 1. Since a probe with the modifications (ie., an analog probe) is coated with a recombinase and is complementary to a first recombinase coated single stranded nucleic acid probe recited in claim 1 and claim 2 does not require that an analog probe recited in claim 1 is different from a second recombinase coated single stranded nucleic acid probe as recited in claim 2, Dayn discloses a second recombinase coated single stranded nucleic acid probe which is substantially complementary to said first probe as recited in claim 2.

Regarding claims 3-6 and 36-39, since Dayn teaches that the probe is any sequences which have substantial homology with each other and with a target DNA sequence (see column 2, lines 27-35), said first single stranded nucleic acid probe is DNA as recited in claims 6 and 39. Since Dayn teaches the DNA sequences of the probes are tethered with some linking groups such as peptide nucleic acid chain (see column 3, third paragraph), Dayn discloses said analog probe comprises peptide nucleic acid as recited in claims 3 and 36. Since Dayn teaches that the DNA sequences of the probes, in the most part, are the naturally occurring nucleotides although a proportion of the nucleotides is modified to enhance stability (see column 2, lines 36-58), Dayn disclose that said analog probe is a fusion sequence comprising nucleoside analogs (ie., peptide nucleic acid) and naturally occurring nucleosides as recited in claims 4 and 37. Since, in the peptide nucleic acid chain taught by Dayn, the phosphates are substituted with glycine (see column 3, third paragraph), said nucleoside analog comprises at least one peptide nucleoside recited in claims 5 and 38.

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Regarding claims 7, 8, 40, and 41, since Dayn teaches that recombinase is recA from *E. coli* (see column 4, lines 3-31), said recombinase is a species of a prokaryotic recombinase wherein said prokaryotic recombinase is a recA recombinase as recited in claims 7, 8, 40, and 41.

Therefore, Dayn teaches all limitations recited in claims 1-8 and 36-41.

### *Conclusion*

6. No claim is allowed.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.



Frank Lu

PSA

February 17, 2004